liquid, a highly reactive solid, or a highly corrosive material.

2. For greenhouse and indoor end-use products, data using the TGAI are required to support manufacturing-use products to be reformulated into these same end-use products or to support end-use products when there is no registered manufacturing-use product. Avian acute oral data are not required for liquid formulations for greenhouse and indoor uses. The study is not required if there is no potential for environmental exposure.

3. Data are required on one passerine species and either one waterfowl species or one upland game bird species for terrestrial, aquatic, forestry, and residential outdoor uses. Data are preferred on waterfowl or upland game bird species for indoor and greenhouse uses.

4. Data are required on waterfowl and upland game bird species.

5. Data are required on one coldwater fish and one warmwater fish for terrestrial, aquatic, forestry, and residential outdoor uses. For indoor and greenhouse uses, testing with only one of either fish species is required.

6. EP or TEP testing is required for any product which meets any of the following conditions:

i. The end-use pesticide will be introduced directly into an aquatic environment (e.g., aquatic herbicides and mosquito larvicides) when used as directed.

ii. The maximum expected environmental concentration (MEEC) or the estimated environmental concentration (EEC) in the aquatic environment is ≥ one-half the LC_{50} or EC_{50} of the TGAI when the EP is used as directed.

iii. An ingredient in the end-use formulation other than the active ingredient is expected to enhance the toxicity of the active ingredient or to cause toxicity to aquatic organisms.

7. Data are required on one freshwater aquatic invertebrate species.

8. Data are generally not required for outdoor residential uses, other than turf, unless data indicate that pesticide residues from the proposed use(s) can potentially enter waterways.

9. Data are required on one freshwater fish species. If the test species is different from the two species used for the freshwater fish acute toxicity tests, a 96 hour LC_{50} on that species must also be provided.

10. Not required when:

i. The octanol/water partition coefficients of the pesticide and its major degradates are < 1,000; or

ii. There are no potential exposures to fish and other nontarget aquatic organisms; or

iii. The hydrolytic half-life is < 5 days at pH 5, 7 and 9.

11. The freshwater fish test species for the TEP testing is the most sensitive of the species tested with the TGAI. A freshwater invertebrate must also be tested with the EP or TEP using the same species tested with the TGAI.

[72 FR 60957, Oct. 26, 2007, as amended at 73 FR 75596, Dec. 12, 2008]

§ 158.250 Experimental use permit data requirements for human exposure.

No data for applicator exposure and post-application exposure must be submitted to support a request for an experimental use permit.

§ 158.260 Experimental use permit data requirements for environmental fate.

All environmental fate data, as described in paragraph (c) of this section, must be submitted to support a request for an experimental use permit.

(a) *Use patterns.* (1) The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood. The aquatic use pattern includes the general use patterns of aquatic food crop, aquatic nonfood residential, and aquatic nonfood outdoors. The greenhouse use pattern includes both food and nonfood uses. The indoor use pattern includes food, nonfood, and residential indoor uses.

(2) Data are also required for the general use patterns of forestry use and residential outdoor use.

(b) *Key.* CR=Conditionally required; NR=Not required; R=Required; PAIRA=Pure active ingredient radiolabeled; TGAI=Technical grade of the active ingredient.

(c) *Table.* The following table shows the experimental use data requirements for environmental fate. The test notes are shown in paragraph (d) of this section.

TABLE—EXPERIMENTAL USE PERMIT ENVIRONMENTAL FATE DATA REQUIREMENTS

Guideline No.	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Greenhouse	Indoors	Forestry	Residential Outdoors		
Degradation Study - Laboratory									
835.2120	Hydrolysis	R	R	R	NR	R	R	TGAI or PAIRA	1
Metabolism Studies - Laboratory									
835.4100	Aerobic soil	R	CR	NR	NR	R	NR	TGAI or PAIRA	2
835.4300	Aerobic aquatic	NR	R	NR	NR	NR	NR	TGAI or PAIRA	--
Mobility Study									
835.1230 835.1240	Leaching and adsorption/ desorption	R	NR	NR	NR	R	NR	TGAI or PAIRA	3

(d) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (c) of this section.

1. Study is required for indoor uses in cases where environmental exposure is likely to occur. Such sites include, but are not limited to, agricultural premises, in or around farm buildings, barnyards, and beehives.

2. Required for aquatic uses for aquatic sites that are intermittently dry. Such sites include, but are not limited to cranberry bogs and rice paddies.

3. Adsorption and desorption using a batch equilibrium method is preferred. However, in some cases, for example, where the pesticide degrades rapidly, soil column leaching with unaged or aged columns may be more appropriate to fully characterize the potential mobility of the parent compound and major transformation products.

[72 FR 60957, Oct. 26, 2007, as amended at 73 FR 75596, Dec. 12, 2008]

§ 158.270 Experimental use permit data requirements for residue chemistry.

All residue chemistry data, as described in § 158.1410, are required for an experimental use permit for which a temporary tolerance under FFDCA section 408(r) is sought. Residue chemistry data are not required for an experimental use permit issued on a crop-destruct basis.

§§ 158.280–158.290 [Reserved]

Subpart D—Product Chemistry

§ 158.300 Definitions.

The following terms are defined for the purposes of this subpart:

Active ingredient means any substance (or group of structurally similar substances, if specified by the Agency) that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, defoliant, or nitrogen stabilizer, within the meaning of FIFRA sec. 2(b).

End-use product means a pesticide product whose labeling:

(1) Includes directions for use of the product (as distributed or sold, or after combination by the user with other substances) for controlling pests or defoliating, desiccating or regulating growth of plants, or as a nitrogen stabilizer, and

(2) does not state that the product may be used to manufacture or formulate other pesticide products.

Formulation means:

(1) The process of mixing, blending, or dilution of one or more active ingredients with one or more other active or inert ingredients, without an intended